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10/599,306	09/25/2006	David Becker	US040173US	1780

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EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3768	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,306	BECKER ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/25/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 3 recites the limitation "wherein transducer mount assembly has a proximal termination within three inches of the distal end of the shaft section" in lines 2 – 4 which lacks proper antecedent basis from the specification.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 102(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application, or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed provisional application, Application No. 60/559,321, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Specifically, Claim 3 recites the limitation "wherein transducer mount assembly has a proximal termination within three inches of the distal end of the shaft section" in lines 2 – 4, which is not supported by the disclosure of either 60/559,321 nor of the disclosure by the present application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. ***Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll, Jr, et al. (US 5,882,302) in view of Magnusson (US 4,007,735).***

Regarding claims 1 and 2, *Driscoll et al.* discloses an ultrasonic intracavity probe (**fig. 2**) for scanning a volumetric region from within the body comprising: (a) a handle section to be held during use of the probe (***handle region*, *32***), near *proximal region* (***16***); and (b) a shaft section having a distal end (***18***) which is to be inserted into a body cavity during use of the probe. It is the area between handle section and distal end of the entire probe housing (***11***)

Driscoll et al. also discloses a pivotally mounted transducer located in the distal end of the shaft section, wherein the transducer (***45***) rotates about an axis of a transducer region (***30***) (*col. 8, lines 19 - 21*). Additionally, annularly phased arrays are used – via incorporation of *Driscoll et al.'s* ***US patent 5,520,188*** (*col. 8, lines 50 – 58*).

A motor (*rotational motor - **fig. 5., 66***), located in the handle section, provides this pivoting motion to the transducer member relative to the probe housing. A drive mechanism (cantilever) coupled to the motor and the array transducer acts to move the array transducer during scanning; that is, the transducer is rotable within the housing of the probe (*col. 7, lines 63 - 67*). Please refer to ***Figure 2***, wherein there is depicted a rod coupled to the motor (***34***) on one end, and coupled to the transducer (***45***) on the other end.

With respect to claims 1 and 2 and the liquid bath, Driscoll et al. discloses a liquid bath (*coupling fluid*) located in the distal end of the shaft, a portion of which is located between the array transducer and the distal end of the shaft during scanning (*col. 8, lines 59 - 61*). The coupling fluid is contained within the transducer mount assembly, wherein the assembly comprises the transducer region (***fig. 3, 30***).

However, Driscoll et al. differs from Claim 1 in that he does not specifically disclose that the center of gravity of the probe is located in the handle section.

Nonetheless, as *Magnusson* explains and would be obvious to one of ordinary skill in the art, the center gravity would be located at the handle section of the probe, where the rotating motor is located. (Magnusson teaches an intracavity probe with a piston motor (**20**) of the probe is located at the handle section of the probe. This is opposite of the location of a vibrator (***16***), located at the distal end of the probe (***fig. 4;*** *Abstract;* and *col. 2, lines 5 – 11*)).

Accordingly, Magnusson complements Driscoll et al. by providing a handle portion with as small vibration amplitude as possible and minimizing the amount of discomfort to the operator of the probe while operating the probe.

Therefore, it would be prima facie obvious to combine Driscoll et al. with Magnusson to obtain a intracavity probe comprising a center of gravity situated at the handle section of the probe while still ensuring operator comfort to obtain the instant invention in claims 1 and 2.

2. ***Claims 3 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll, Jr, et al. (US 5,882,302) in view of Magnusson (US 4,007,735)*** **as applied to claims 1 and 2 above, and further in view of Larson et al. (US 6,039,694).**

Regarding claims 3 – 10, Driscoll et al. in view of Magnusson teaches an ultrasonic intracavity probe comprising transducer mount assembly located in the distal end of the shaft of the probe and a liquid bath located within the transducer assembly.

Driscoll et al. and Magnusson differ from Claim 3 in that Driscoll et al. and Magnusson do not specifically disclose that the transducer mount assembly has a proximal termination

within three inches of the distal end of the shaft section. Driscoll et al. and Magnusson further differ from Claim 3 in that Driscoll et al. and Magnusson also do not specifically disclose that 75% of the liquid bath is contained within the transducer mount assembly; or that liquid bath has a volume of "less than 25 cc of liquid," or "less than 10 cc of liquid," or "approximately 6 cc of liquid;" or that 90% of the liquid bath in the most distal 25% of the length of the shaft section.

Nonetheless, Larson et al. teaches a coupling sheath for ultrasound transducer that is conformal and performs as if integral to the transducer mount assembly. Furthermore, the coupling sheath comprises preferably about 70 to 95% biocompatible liquid (Abstract).

Accordingly, Larson et al. complements Driscoll et al. and Magnusson by teaching a homogenous, solid, elastic, biocompatible sheath comprising biocompatible fluid that renders properties to the sheath, resulting in desirable levels of acoustic coupling (Abstract).

Therefore, it would be prima facie obvious to modify the coupling fluid of Driscoll et al. (in view of Magnusson) with the coupling sheath of Larson et al. to obtain an ultrasound intracavity probe that leaves no harmful residue when used with the body orifices and remains lubricous when in contact with bodily fluids (Abstract).

Furthermore, it would be obvious to one of ordinary skill in the art that, of the three inches of the distal end as claimed in Claim 3, to have the transducer mount assembly terminate within one and one-half inches of the distal end of the probe to achieve optimal results with respect to localizing the center of gravity in the handle section of the probe; or to provide the specifications as claimed in claims 4 – 10.

Furthermore, it would be obvious to one of ordinary skill in the art to dispose the coupling sheath within one and one-half inches of the distal end of the probe for optimal results in ensuring that the center of gravity remains in the handle section of the probe.

3. ***Claims 11 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll, Jr, et al. (US 5,882,302) in view of Magnusson (US 4,007,735)*** **as applied to Claim 1 above, and further in view of Bushek et al. (US 6,315,710).**

Regarding claims 11 – 16, Driscoll et al., in view of Magnusson, discloses a transducer mount assembly, wherein the transducer array (**45**) is cantilevered. (*col. 8, line 17 - 20*). ***Figures 2*** and ***3*** depict that the cantilever has a main body that extends into the distal region of the shaft. The transducer array (**45**) is mounted to the cantilever, which extends from the handle such that the transducer array is free to rotate or pivot about the axis of transducer region (**30**). Transducer array and cantilever from the transducer member (**28**) (***figs. 2 and 4***).

Driscoll et al. in view of Magnusson differs from claims 11 – 16 in that Driscoll et al. in view of Magnusson does not disclose specifically that the main body of the transducer mount assembly is formed of material lighter than stainless steel.

However, Bushek et al. teaches a hearing device, insertable into a cavity such as a ear, comprising a transducer mount assembly (fig. 11, 220) formed from a material other than stainless steel such as polycarbonate, silicone, titanium, etc. (col. 13, lines 60 – 67).

Accordingly, Bushek et al. complements Driscoll et al. in view of Magnusson by teaching a mount assembly that the rotation and delicate positioning of the transducer (col. 13, lines 52 – 59). Applicant should note that although Bushek et al. teaches that the transducer can be secured

by additional means such as a screw, this does not teach away from the feature that the transducer mount assembly still allows the rotation of transducer.

Therefore, it would be prima facie obvious to combine Driscoll et al. in view of Magnusson with Bushek et al. to obtain a transducer mount assembly made of materials lighter than stainless steel for rotability of the transducer to obtain the present invention in the instant claims 11 – 16.

With further respect to Claim 12, Driscoll et al. discloses a transducer cradle – (angular pieces of transducer member (**28**)), which supports transducer array (**45**) and radiating surfaces (*col. 8, lines 40 – 58; col. 9, lines 53 – 60; and* (**fig. 5**)).

With further respect to claims 13 and 14, transducer cradle includes a solid body located behind array transducer which displaces volume of coupling fluid; it is shaped so that it passes more easily through the liquid bath (***fig. 3***).

With further respect to claims 15 and 16, Driscoll et al. teaches that the transducer mount assembly includes wear surfaces, wherein wear surfaces are part of the drive mechanism (gig. 3, jagged edges adjacent to positioning mechanism (**34**)). Bushek et al. teaches that components of the transducer mount assembly may be formed of materials such as stainless steel (col. 13, lines 60 – 67).

4. ***Claims 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll, Jr, et al. (US 5,882,302) in view of Magnusson (US 4,007,735)*** **as applied to Claim 1 above, and further in view of Bushek et al. (US 6,315,710) as applied to Claim 11, in further view of Fukumoto et al. (US 6,621,065 B1).**

Regarding Claim 17 – 20, Driscoll et al. in view of Magnusson teaches an intracavity probe comprising a transducer mount assembly.

Driscoll et al. in view of Magnusson, in further view of Bushek et al. teaches that components of the transducer mount assembly may be made of materials lighter than stainless steel.

However, Driscoll et al. in view of Magnusson, in further view of Bushek et al. differs from claims 17 – 20 in that Driscoll et al. in view of Magnusson, in further view of Bushek et al. does not teach that that the weight is less than 400 grams, or less than 300 grams, or approximately 250 grams; or that shaft of the intracavity probe is made with materials at least equal to the density of the stainless steel components of the drive mechanism for optimal results with respect to localizing the center of gravity in the handle section of the probe

Nevertheless, Fukumoto et al. teaches an imaging probe may comprise a mass of 500 grams or less (hence less than 400 grams) (col. 7, lines 22 - 26). Fukumoto et al. also teaches that the probe may be made of a material such as magnesium alloy, which allows the light mass of the probe.

Furthermore, as is known in the art, magnesium alloy comprises a density that is less than the density of stainless steel.

Accordingly, Fukumoto et al. complements Driscoll et al. in view of Magnusson, in further view of Bushek et al., by teaching that magnesium alloy is malleable in that it can be thinned for scalability purposes and has a property for shielding electromagnetic waves (col. 5, lines 54 – 55). As is known in the art, electromagnetic waves may commonly occur in medical imaging settings. Additionally, as would be obvious to one of ordinary skill in the art, Fukumoto

et al.'s imaging probe may be scaled so that it can fit with a natural cavity of a patient. As discussed above, magnesium alloy's scalability allows as msuch.

Therefore it would be prima facie obvious to combine Driscoll et al. in view of Magnusson in further view of Bushek et al. with Fukumoto et al. to obtain an imaging probe that can be made of magnesium alloy for less mass and scalability purposes obtain the present invention in the instant claims 17 – 20.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: *Englehart et al.* (***US 4,917,096***) for transducer disposed in ultrasound coupling fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768